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www.fda.gov/oc/bioterrorism/titleIII.html#registration

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April 3, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0276
ATTN: Docket No. 02N-0278

Subject:

Rules proposed by the Department of Health and Human Services' Food and Drug Administration (FDA) under the *[US] Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Bioterrorism Act)

Docket No. 02N-0276, Section 305 (Registration)

Docket No. 02N-0278, Section 307 (Prior Notice)

To Whom It May Concern:

We appreciate the opportunity to submit comments to the above referenced items on behalf of the Canadian Horticultural Council.

Sincerely,

Anne Fowlie
Executive Vice President
Canadian Horticultural Council

attachment

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April 4, 2003

**Comments of The Canadian Horticultural Council on
rules proposed by the Department of Health and Human Services' Food
and Drug Administration (FDA) under the [U.S.] *Public Health Security and
Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)***

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The Canadian Horticultural Council welcomes and appreciates the opportunity to provide comments on the above-referenced notices of proposed rulemaking as published by the Food and Drug Administration (FDA), Department of Health and Human Services, in the *Federal Register* of February 3, 2003. We respectfully request that this single submission be considered for both dockets.

While we support the objectives of the [U.S.] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)* and share concerns relative to perimeter and border security as well as food safety we take issue with certain aspects of the proposed rules.

Consideration must be given to the unique circumstances of movements across the Canada-United States border and the highly integrated nature of the economies of the two countries. We enjoy a relationship Rules must not result in an environment which is more trade restrictive than necessary to meet the objectives of the *Bioterrorism Act*. Compliance with international trade obligations must be considered. The concerns expressed through the comment process and the manner in which they are addressed will have an impact on meeting the objective of the initiative.

About The Canadian Horticultural Council

The Canadian Horticultural Council (CHC) is a voluntary, not-for-profit, national association representing the diverse sector of Canadian agriculture known as horticulture. The CHC has been committed to promoting the interests of its members since 1922.

The CHC's members are primarily involved in the production and packing of over 120 horticulture crops comprised of fruit, vegetables, flowers and ornamental plants. We have 105 members from across Canada as well as three associate members from the United States.

The CHC's mission is a commitment to advance the growth and economic viability of horticulture by encouraging cooperation and understanding to build national consensus on key issues so as to deliver unified and clear representation to governments and other national and international parties.

Industry and trade statistics on our sector of Canadian agriculture, which are available through government and private sector sources in both Canada and the United States, clearly demonstrate the critical importance of our ability to move our highly perishable fresh products in a timely and efficient manner. We are an industry that relies heavily on bi-lateral trade, and as such it is critical that the efficient movement of perishable products between the United States, Mexico and Canada is maintained.

Buyer consolidation the United States and Canada - particularly in the food industry - has resulted in increased pressures on suppliers of perishable commodities. In an effort to improve quality, reduce claims, and reduce

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overheads associated with warehousing inventory “just in time delivery” is the normal course of doing business. The success of the “just in time delivery” model depends on suppliers being able to react quickly to market requirements. Orders are regularly altered by the buyer right up until the time of shipment in order to ensure opportunities are maximized at the retail and food service level.

The CHC and its members have undertaken to develop and implement numerous programs and initiatives to address the safety and security of our products. Examples include the On-Farm Food Safety Guidelines for Fresh Fruit and Vegetables in Canada as well as the Canadian Partners in Quality Program. There are numerous others.

Docket No. 02N-0276 **Registration of Food Facilities**

The Canadian Horticultural Council's main concern with this regulation as it is proposed relates to the need for a precise definition of what Canadian farms/facilities must be registered as food facilities. That is:

- ?? will each member of a producer cooperative be required to be registered;
- ?? will a farm operation with a packing shed be treated differently than a farm which only transports products;
- ?? clarification of such terms as packer; furthermore, what about packing into tote bins and bulk containers;
- ?? clarification of such terms as manufacturer, processor and holder of fresh fruits and vegetables; and
- ?? will Canadian exporters of fresh fruits and vegetables who trans-ship product through the United States to Mexico or offshore markets, require registration?

There also are concerns related to the increased administrative burden on exporters of yet another agency to administer and require more forms to be completed and processed. It does not appear to make sense to create yet another registration system when Canadian exporters of fresh fruit and vegetables are already providing the a multitude of information to such organizations as the customs authorities in both Canada and/or the United States, the Canadian Food Inspection Agency and others such as the PACA (in the United States) Dispute Resolution Corporation (Canada/US/Mexico). It would be far more efficient to share information between such bodies or work toward a joint or common registration system so as to avoid duplication. Infrastructure costs will be very significant for all; significant investment will be required and effort must be made to mitigate this aspect wherever possible.



Docket No. 02N-0278
Prior Notice of Imported Food Shipments

In order to be effective, the prior notice rule must take into account the unique commercial environment present at the Canada-United States border, which includes large volumes of just-in-time deliveries of perishable food products.

The Canadian Horticultural Council's main concern with this proposed regulation relates primarily to its impact on the highly perishable nature of most fresh fruits and vegetables. Products such as leafy vegetables, green onions, cabbage, broccoli, cauliflower, new potatoes, sweet cherries and berries are normally harvested within hours of arrival at the border and cannot withstand any delays, especially during the extreme heat of summer and early fall when these products are in season. This list is not all-inclusive as there are many, many crops.

The proposed rule requires notification no later than noon the day before the fresh food product is to arrive at the border crossing. That essentially means there would be a minimum of 12 hours notice prior to arrival at the border and more importantly what amounts to a 36-hour delay, if notice were not given until say 12:01 p.m. on the day an order is received. This will prevent delivery to the United States of Canadian fresh fruits and vegetables that are ordered on the same day as the shipment is to be made for "just in time" delivery. The vast majority of Canadian fruit and vegetable production is located within two to three hours by truck of the United States border. The proposed time frames, including the ability to make amendments until up to two hours before arrival are not workable for much of the Canadian fresh produce industry. This is particularly pertinent for those located less than two hours from the border. The nature of the fresh produce industry is such that changes in the nature and volume of the load can and do occur up to the actual loading time.

A much clearer understanding or definition of what circumstances would necessitate the filing of an amendment must be established.

There is also a concern that if the FDA's electronic notification system is down for whatever reason, it will create impossible delays for highly perishable fresh fruits and vegetables. The volume and number of movements that take place on a daily basis speak to the reliance on such systems. Additionally, we do not support the establishment of an additional coding system. Rather than develop an additional set of codes that will create confusion, mistakes and essentially duplicate information we suggest that the current system of HS codes that are already provided to U.S. Customs be streamlined.

Summary

We are indeed fortunate to have sophisticated food safety systems in Canada and the United States. We must work together to establish a balance that will maintain our unique and vitally important trade and a relationship that has long been the envy of the world. There is also a need, and indeed opportunities, to build on the unique and strong working relationships that

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exist between our two countries to further enhance initiatives such as the Ridge-Manley "Smart Border" process. We all have a shared responsibility to ensure the success of achieving the goals.

In summary, there is a major concern about the proposed rules and their impact on a key sector of our respective economies and societies. However well intentioned the initiative may be, there are serious issues that must be carefully considered and unintended impacts and circumstances that will no doubt arise. The ability to amend rules quickly is critical. The rules which will be implemented later this year, along with their respective new requirements, despite careful design, could have immediate and significant and unintended consequences for the all parties, particularly the USFDA's operations, Canadian growers, packers and shippers, carriers, United States importers and consumers, and the smooth operation of the Canada-United States border in general. Lessons learned and better ways of achieving the objectives should be quickly incorporated into the rules.

With the creation of these new rules, extensive new information requirements and the creation of new electronic supporting systems, it will be even important for the USFDA to promote and conduct education and outreach efforts as implementation proceeds.

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